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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,666	08/01/2005	Christophe de Romeuf	065691-0387	7253

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

DAHLE, CHUN WU

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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03/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,666	Applicant(s) DE ROMEU ET AL.	
	Examiner CHUN DAHLE	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 2, 2008, has been entered.

2. Applicant's amendment to the claims, filed on January 2, 2008, is acknowledged.

Claims 1-12 and 14 have been canceled.

Claim 13 are pending and currently under consideration.

3. This Office Action is in response to Applicant's amendment to the claims and remarks filed on January 2, 2008.

4. In view of applicant's amendment to the claims, filed on January 2, 2008, the previous rejection under 35 U.S.C. 112, second paragraph has been withdrawn.

5. In view of applicant's amendment to the claims, filed on January 2, 2008, the previous rejections under 35 U.S.C. 112, first paragraph, enablement and written description have been withdrawn.

6. In view of applicant's amendment to the claims, filed on January 2, 2008, the previous rejection under 35 U.S.C. 102(b) has been withdrawn.

7. The reference Amirzargaret al. (Pathology Oncology Research. 2007. 13;1:47-51) submitted on Exhibit 1, filed on January 2, 2008, has been listed on PTO-892. A copy of the reference will not be provided.

8. Applicant is reminded that the foreign priority documents FRANCE 02/11415 and FRANCE 02/11416 upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for the instant claims. Specifically, insufficient support was identified for the limitation of "chronic myeloid leukemia". Consequently, the claims have been accorded the foreign priority of the filing date of the FRANCE 03/07066, i.e. 06/12/2003 (see page 3 of the previous Office Action mailed on January 5, 2007).

Should applicant disagree with the Examiner's factual determination above, it is incumbent upon applicant to provide a showing that specifically supports the instant claim limitations.

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tso et al. (US Patent 6,894,149) in view of Ogawa et al. (EP 1229125, published on July 8, 2002, reference on PTO-892, mailed on January 5, 2007).

Tso et al. teach a method for treating diseases such as chronic myeloid leukemia by administering humanized anti-HLA-DR monoclonal antibody (e.g. see columns 4 and 7-8). Tso et al. further provided methods of genetically engineering of the anti-HLA-DR antibodies and working examples of method of making anti-HLA-DR antibodies using conventional hybridoma techniques (e.g. see columns 6 and 14).

The reference teachings differ from the claimed invention by not describing humanized anti-HLA-DR antibody made in rat myeloma YB2/0 cells.

Ogawa et al. teaches that antibodies e.g. humanized antibodies, made in YB2/0 host cells, have a higher antibody-dependent cell-mediated cytotoxic activity (ADCC) and are useful as a pharmaceutical agents for treating diseases such as cancer (see entire document, particularly columns 3-5). Ogawa et al. teach that cDNA encoding antibodies can be cloned from known hybridomas and expressed in YB2/0 cells and the antibodies can be produced in serum free environment (e.g. see column 5). Given the referenced antibodies are made in the same host cells (YB2/0) as the claimed antibodies, the claimed limitation of the glycan structures would be inherent properties of the antibodies taught by Ogawa.

Given the availability of the hybridomas producing anti-HLA-DR antibodies together with general immunoglobulin gene cloning and expression strategies, it would have been have been a matter of routine experimentation well within the ordinary skill level of art to make humanized anti-HLA-DR antibodies in rat myeloma cell YB2/0.

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One of ordinary skill in the art would have been motivated to make humanized anti-HLA-DR antibodies taught by Tso et al. in YB2/0 cells for enhanced ADCC function for therapeutic regimens in humans in view of the teachings from Ogawa et al. of the advantage of producing antibodies in YB2/0 cells. One of ordinary skill in the art would have had a reasonable expectation of success in generating humanized anti-HLA-DR antibodies in YB2/0 cells and used said antibodies in a method of treating chronic myelocytic leukemia. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary. .

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Eileen O'Hara can be reached 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/

Primary Examiner, Art Unit 1644

Chun Dahle (formerly Chun Crowder)

Patent Examiner

March 16, 2008